Department of Veterans Affairs **VHA DIRECTIVE 2004-052**
Veterans Health Administration
Washington, DC 20420 **September 29, 2004**

INFLUENZA VACCINE RECOMMENDATIONS FOR 2004-2005

1. PURPOSE: This Veterans Health Administration (VHA) Directive provides policy and implementation guidance on the use of influenza vaccine for 2004-2005.

2. BACKGROUND

a. The influenza vaccination program is an essential component of the Veterans Health Administration (VHA) health and disease prevention programs. Influenza is a cause of significant morbidity and mortality in the United States. Considering that epidemics of respiratory disease typically occur during the winter months, there is concern that there may be an increase in cases of influenza, Severe Acute Respiratory Syndrome (SARS), or other influenza-like illnesses. Because symptoms of these illnesses and influenza are similar, the potential for clinical and operational impact on the VHA health care system this winter could be substantial. The influenza vaccine is the most effective way to protect against influenza disease and resultant potentially severe complications. Influenza vaccination is a safe and cost-effective means for preventing and controlling influenza. ***NOTE:*** *Influenza vaccination rates are monitored in the VHA performance measurement system.*

b. The trivalent influenza vaccine prepared for the 2004-2005 season includes A/Fujian/411/2002 (H3N2)-like, A/New Caldeonia/20/99 (H1N1)-like, and B/Shanghai/361/2002-like antigens.

c. Information is provided in Attachment A that includes the use of influenza vaccine, groups targeted for vaccination, contraindications, potential side effects associated with vaccination, vaccine dosage, route of administration, and scheduling of doses.

3. POLICY: It is VHA policy to base the influenza vaccination program on recommendations of the Centers for Disease Control and Prevention (CDC) Advisory Committee on Immunization Practices (ACIP) as published in Morbidity and Mortality Weekly Report (MMWR), while focusing on VHA specific issues in accordance with statues or other regulations, and policies governing vaccine administration to patients and employees.

4. ACTION: VHA facility Directors are responsible for implementing an influenza vaccination program in accordance with this Directive and ensuring:

a. **Patient Consent and Documentation**. All persons receiving influenza vaccine need to receive information about the vaccine (e.g., CDC's Vaccine Information Statement on Influenza Vaccine). The practitioner who has primary responsibility for the patient or who will perform the procedure must explain in language understandable to the patient or surrogate the nature of the procedure, expected benefits, reasonably foreseeable associated risks, complications or side effects, anticipated results if influenza vaccine is not given, and document the non-signature

informed consent process in the medical record. Documentation is to also include the date of administration of the vaccine, the lot number, manufacturer, route and site of vaccine administration, and name and title of the individual administering the vaccine.

b. **Employee Consent and Documentation.** Any employee who receives influenza vaccine will receive information about the vaccine (e.g., CDC's Vaccine Information Statement on Influenza Vaccine). The information should include the nature of the procedure, expected benefits, reasonably foreseeable associated risks, complications or side effects and anticipated results if influenza vaccine is not given. Documentation is to include employee receipt of information about the vaccine, the date of administration of the vaccine, lot number, manufacturer, route and site of vaccine administration, and name and title of the individual administering the vaccine. Documentation concerning influenza vaccine will be in accordance with VA Handbook 5019, Part V. Provision of influenza vaccine to employees, as appropriate, will be at no expense to the employee. Inactivated influenza vaccine is to be used for the employee influenza vaccination program.

c. **Adverse Events Related to Vaccine Use are Reported.** Facilities will complete FDA Form 3500, Med Watch, for all serious adverse drug events relating to biologicals. Reports of adverse events related to vaccine use should be reported to FDA on VAERS – 1, Vaccine Adverse Event Form.

d. **Vaccine Shortage.** Shortfalls of vaccines are not expected during the 2004-2005 influenza season. If an influenza vaccine delay and/or shortage occur, VHA facilities at the local level need to develop a prioritization plan that maximizes protection of the patients most likely to develop serious and life-threatening complications from influenza.

5. REFERENCES

a. CDC. Prevention and Control of Influenza: Recommendations of the Advisory Committee on Immunization Practices (ACIP), MMWR May 28, 2004/Vol. 53/RR6; 1-40. http://www.cdc.gov/mmwr/PDF/rr/rr5306.pdf

b. CDC. Inactivated Influenza Vaccine (5/24/04) Vaccine Information Statement. http://www.cdc.gov/nip/publications/VIS/vis-flu.pdf

c. "Maximizing Vaccination Rates for Veterans with SCI&D," VA QUERI Quarterly Newsletter, Vol. 3: No. 4; March, 2002.

d. VHA Handbook 1004.1 VHA Informed Consent for Clinical Treatment and Procedures, January 29, 2003.

e. VA Handbook 5019 Occupational Health Services, April 15, 2002.

f. M-2, Part 1, Chapter 3. Pharmacy and Therapeutics (P&T) Committee.

g. Vaccine Adverse Event Report (VAER). http://www.vaers.org/pdf/vaers_form.pdf

6. FOLLOW-UP RESPONSIBILITY: The Chief Officer, Patient Care Services (11) is responsible for the contents of this Directive. Questions relating to implementation of the influenza vaccination program are referred to the National Center for Health Promotion and Disease Prevention (NCP), telephone (919) 383-7874, extension 234, or extension 222. Questions relating to influenza and/or influenza vaccine are referred to the Infectious Diseases Program Office, telephone number (513) 475-6398. Questions pertaining to legal issues (including consent) are referred to the appropriate Regional Counsel.

7. RECISSION: VHA Directive 2003-058 is rescinded. This Directive expires on September 30, 2009.

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Attachment

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ATTACHMENT A

INFORMATION ABOUT THE INFLUENZA VIRUS VACCINE FOR 2004-2005

1. TARGET GROUPS FOR VACCINATION (In accordance with statutes or other regulations, and policies governing vaccine administration to VHA patients and employees.)

a. **Persons at Increased Risk for Complications.** Vaccination with inactivated influenza vaccine is recommended for the following persons who are at increased risk for complications from influenza:

(1) Persons ages 65 years or older;

(2) Residents of nursing homes, other chronic-care facilities that house persons of any age who have chronic medical conditions, and residents of domiciliaries;

(3) Adults who have chronic disorders of the pulmonary or cardiovascular systems, including asthma;

(4) Adults who have required regular medical follow-up or hospitalization during the preceding year because of chronic metabolic diseases (including diabetes mellitus), renal dysfunction, hemoglobinopathies, or immunosuppression (including immunosuppression caused by medications or by human immunodeficiency virus [HIV]); and

(5) Women who will be pregnant during the influenza season.

b. **Persons Aged 50-64 Years.** Vaccination is recommended for persons in this group because the group has an increased prevalence of persons with high-risk conditions.

c. **Persons Who Can Transmit Influenza to Those at High-Risk.** Vaccination of caregivers and household contacts of persons at high risk for complications from influenza is recommended. Health care workers should be vaccinated against influenza annually. The following groups should be vaccinated:

(1) Physicians, nurses, and other personnel in both hospital and outpatient-care settings, including medical emergency response workers (e.g., paramedics and emergency medical technicians);

(2) Employees of nursing homes, chronic-care facilities, and domiciliaries who have contact with patients or residents;

(3) Employees of assisted living and other residences for persons in groups at high risk;

(4) Persons who provide home care to persons in groups at high risk; and

(5) Household contacts of persons in groups at high risk.

d. **Vaccination of Specific Populations**

(1) **Pregnant Women.** Because of the increased risk for influenza-related complications, women who will be pregnant during the influenza season should be vaccinated. Vaccination can occur in any trimester.

(2) **Breastfeeding Mothers.** Influenza vaccine does not affect the safety of mothers who are breastfeeding or their infants. Breastfeeding does not adversely affect the immune response and is not a contraindication for vaccination.

(3) **Persons Infected with HIV.** Limited information is available regarding the frequency and severity of influenza illness or the benefits of influenza vaccination among persons with HIV infection. Because influenza can result in serious illness, and because influenza vaccination can result in the production of protective antibody titers, vaccination will benefit HIV-infected persons, including HIV-infected pregnant women.

(4) **Spinal Cord Injury & Disease (SCI&D).** Persons living with SCI&D are at risk of developing pulmonary complications and are more likely to die as a result of influenza or pneumonia than persons in the general population; therefore, vaccination needs to be emphasized for this high-risk group.

(5) **Travelers**

(a) The risk of exposure to influenza during travel depends on the time of year and destination. In the tropics, influenza can occur throughout the year. In the temperate regions of the Southern Hemisphere, the majority of influenza activity occurs during April through September. In the temperate climate zones of the Northern and Southern Hemispheres, travelers also can be exposed to influenza during the summer, especially when traveling as part of large organized tourist groups that include persons from areas of the world where influenza viruses are circulating.

(b) Persons at high risk for complications of influenza who were not vaccinated with influenza vaccine during the preceding fall or winter need to consider receiving influenza vaccine before travel, if they plan travel:

1. To the tropics,

2. With large organized tourist groups at any time of the year, or

3. To the Southern Hemisphere during April through September.

(6) **General Population**

(a) In addition to the groups for which the annual influenza vaccination is recommended, physicians need to administer influenza vaccine to any person who wishes to reduce the likelihood of becoming ill with influenza, depending on vaccine availability.

(b) Persons who provide essential community services need to be considered for vaccination to minimize disruption of essential activities during influenza outbreaks.

(c) Students or other persons in institutional settings (e.g., those who reside in dormitories) need to be encouraged to receive the vaccine to minimize the disruption of routine activities during epidemics.

2. PERSONS WHO SHOULD NOT BE VACCINATED WITH INACTIVATED INFLUENZA VACCINE

a. Inactivated influenza vaccine should not be administered to persons known to have anaphylactic hypersensitivity to eggs or to other components of the influenza vaccine without first consulting a physician (see par. 5, Side Effects and Adverse Reactions of Inactivated Influenza Vaccine). Prophylactic use of antiviral agents is an option for preventing influenza among such persons. However, persons who have a history of anaphylactic hypersensitivity to vaccine components but who are also at risk for complications from influenza can benefit from vaccine after appropriate allergy evaluation and desensitization. ***NOTE:*** *Information about vaccine components, can be found in package inserts provided by each manufacturer.*

b. Persons with acute febrile illness usually should not be vaccinated until their symptoms have abated. However, minor illnesses with and without fever do not contraindicate use of influenza vaccine.

3. TIMING OF ANNUAL VACCINATION WITH INACTIVATED INFLUENZA VACCINE

a. Persons planning substantial organized vaccination campaigns need to consider scheduling these events after mid-October because the availability of vaccine in any location cannot be ensured consistently in the early Fall. Scheduling campaigns after mid-October minimizes the need for cancellations because the vaccine is unavailable. To the extent feasible, campaigns conducted before November need to focus efforts on vaccination of persons ages 50 and older at increased risk for influenza-related complications, health care workers, and household contacts of persons at high-risk.

b. While the optimal time to vaccinate is usually during October-November, it is recommended that vaccine providers focus their vaccination efforts in October, and earlier primarily on persons age 50 and older, persons younger than age 50 who are at increased risk for influenza-related complications, household contacts of persons at high-risk (including out-of-home caregivers), and health care workers.

c. To avoid missed opportunities for vaccination of persons at high-risk for serious complications, such persons need to be offered the vaccine beginning in September during routine health care visits or during hospitalizations, if the vaccine is available.

d. Efforts to vaccinate other persons who wish to decrease their risk for influenza infection should begin in November.

e. In facilities housing elderly persons (e.g., nursing homes), vaccination before October generally is to be avoided, because antibody levels in such persons can begin to decline within a limited time after vaccination. All residents within a nursing home and other residential long-term care facilities need to be vaccinated at one time, preceding the influenza season. Residents admitted through March, after completion of the facility's vaccination program, need to be vaccinated at the time of admission, if not previously vaccinated during current season.

f. To improve vaccine coverage, influenza vaccine need to continue to be offered in December and throughout the influenza season as long as vaccine supplies are available, even after influenza activity has been documented in the community. ***NOTE:*** *In the United States, seasonal influenza activity can begin to increase as early as October or November, but influenza activity has not reached peak levels until late December-early March, in the majority of recent influenza seasons.*

4. VACCINE DOSAGE OF INACTIVATED INFLUENZA VACCINE

Adult patients need to receive one intramuscular dose in the deltoid muscle per dosage and information contained in the manufacturer's package insert. A needle length equal to or greater than 1 inch can be considered for adults because needles less than 1 inch might be of insufficient length to penetrate muscle tissue in certain adults.

5. SIDE EFFECTS AND ADVERSE REACTIONS OF INACTIVATED INFLUENZA VACCINE

a. When educating patients regarding potential side effects, clinicians need to emphasize that:

(1) Inactivated influenza vaccine contains noninfectious killed viruses and cannot cause influenza; and

(2) Coincidental respiratory disease unrelated to influenza vaccinations can occur after vaccination.

b. **Local Reactions**

(1) The most frequent side effect of vaccination is soreness at the vaccination site that lasts less than 2 days.

(2) These local reactions typically are mild and rarely interfere with the person's ability to conduct usual daily activities.

c. **Systemic Reactions**

(1) Fever, malaise, myalgia, and other systemic symptoms can occur after vaccination with inactivated vaccine and most often affect persons who have had no prior exposure to the influenza virus antigens in the vaccine (e.g., young children). These reactions begin 6-12 hours after vaccination and can persist for 1-2 days.

(2) Immediate – presumably allergic – reactions (e.g., hives, angioedema, allergic asthma, and systemic anaphylaxis) rarely occur after influenza vaccination. These reactions probably result from hypersensitivity to certain vaccine components; the majority of reactions probably are caused by residual egg protein. Although current influenza vaccines contain only a limited quantity of egg protein, this protein can induce immediate hypersensitivity reactions among persons who have severe egg allergy. Persons who have had hives or swelling of the lips or tongue, or who have experienced acute respiratory distress or collapse after eating eggs need to consult a physician for appropriate evaluation to help determine if vaccine should be administered. Persons with documented immunoglobulin E (IgE)-mediated hypersensitivity to eggs, including those who have had occupational asthma or other allergic responses to egg protein, might also be at increased risk for allergic reactions to influenza vaccine, and consultation with a physician is to be considered.

(3) Hypersensitivity reactions to any vaccine component can occur. Although exposure to vaccines containing thimerosal can lead to induction of hypersensitivity, the majority of patients do not have reactions to thimerosal when it is administered as a component of vaccines, even when patch or intradermal tests for thimerosal indicate hypersensitivity. When reported, hypersensivity to thimerosal usually has consisted of local, delayed-type hypersensitivity reactions.

d. **Guillain-Barré Syndrome (GBS)**

(1) Investigations to date indicate no substantial increase in GBS associated with influenza vaccines (other than the swine influenza vaccine in 1976) and that, if influenza vaccine does pose a risk, it is probably slightly more than one additional case per million persons vaccinated.

(2) The potential benefits of influenza vaccination in preventing serious illness, hospitalization, and death substantially outweigh the possible risks for experiencing vaccine-associated GBS. The average case fatality ratio for GBS is 6 percent and increases with age. No evidence indicates that the case fatality ratio for GBS differs among vaccinated persons and those not vaccinated.

(3) The incidence of GBS among the general population is low, but persons with a history of GBS have substantially greater likelihood of subsequently experiencing GBS than persons without such a history. Thus, the likelihood of coincidentally experiencing GBS after influenza vaccination is expected to be greater among persons with a history of GBS than among persons

with no history of this syndrome. Whether the influenza vaccination specifically might increase the risk for recurrence of GBS is unknown; therefore, avoiding vaccinating persons who are not at high risk for severe influenza complications and who are known to have experienced GBS within 6 weeks after a previous influenza vaccination is prudent. Although data are limited, for the majority of persons who have a history of GBS and who are at high risk for severe complications from influenza, the established benefits of influenza vaccination justify yearly vaccination.

6. SIMULTANEOUS ADMINISTRATION OF OTHER VACCINES WITH INACTIVATED INFLUENZA VACCINE

Inactivated influenza vaccine co-administration has been evaluated systematically only among adults with pneumococcal polysaccharide vaccine. Adult target groups for influenza and pneumococcal vaccination overlap considerably. For persons at high-risk who have not previously been vaccinated with pneumococcal vaccine, health care providers need to strongly consider co-administration of pneumococcal polysaccharide and inactivated influenza vaccine. Both vaccines can be administered at the same time at different sites without increasing side effects. ***NOTE:*** *Influenza vaccine is administered each year, whereas pneumococcal vaccine is not.*

7. ANTIVIRAL DRUGS FOR INFLUENZA

a. Antiviral drugs for influenza are an adjunct to influenza vaccine for controlling and preventing influenza. However, these agents are not a substitute for vaccination. Currently there are four licensed influenza antiviral agents available in the United States: amantadine, rimantadine, zanamivir, and oseltamivir.

b. Amantadine and rimantadine are chemically-related antiviral drugs known as adamantanes with activity against influenza A, but not influenza B viruses. Amantadine was approved in 1966 for prophylaxis of influenza A (H2N2) infection and was later approved in 1976 for treatment and chemoprophylaxis of influenza type A virus infections among adults and children ages 1 year old and older. Rimantadine was approved in 1993 for treatment and chemoprophylaxis of influenza A infection among adults and prophylaxis among children.

c. Zanamivir and oseltamivir are chemically related antiviral drugs known as neuraminidase inhibitors that have activity against both influenza A and B viruses. Both zanamivir and oseltamivir were approved in 1999 for treating uncomplicated influenza infections. Zanamivir is approved for treating persons ages 7 years old and older, and oseltamivir is approved for treatment for persons ages 1 year old and older. In 2000, oseltamivir was approved for chemoprophylaxis of influenza among persons ages 13 years old and older.

d. The four drugs differ in pharmacokinetics, side effects, routes of administration, approved age groups, dosages, and costs. ***NOTE:*** *Consult the package inserts provided by the manufacturers for more information on each drug.*

e. VA National Formulary includes the following antivirals for the prophylaxis or treatment of Influenza A exposure; amantadine and rimantadine. The incidences of adverse effects associated with these antivirals appear to be dose related and may require changes in the dosing regimen. Careful consideration to such factors as the patient's age, renal and hepatic function is recommended in determining the antiviral dose. The patient's concomitant medical conditions and potential for drug interactions should also be taken into consideration when prescribing these agents. Additional information on the PBM VANF may be found at http://vaww.pbm.med.va.gov .

8. STRATEGIES FOR IMPLEMENTING RECOMMENDATIONS IN HEALTH CARE SETTINGS

a. **Program Planning.** Successful vaccination programs combine:

(1) Publicity and education for health care workers and other potential vaccine recipients,

(2) A plan for identifying persons at high-risk,

(3) Use of reminder and/or recall systems,

(4) Standing orders programs, and

(5) Other strategies to remove barriers that prevent persons from receiving vaccine.

b. **Department of Veterans Affairs (VA) Medical Center Employees**

(1) Measures need to be taken to provide all health care workers convenient access to influenza vaccination at the work site, free of charge, as part of the VA Occupational Health Services Program, because employees may transmit influenza to patients. Inactivated influenza vaccine needs to be offered to employees through the Occupational Health Unit.

(2) Vaccination records must be maintained in the Occupational Health Unit or in a separate locked area controlled by Human Resources Management Office in accordance with VA Handbook 5019, Part V.

(3) Expenses involved in the program need to be kept at a minimum; therefore, the use of centrally-procured vaccine vials is recommended instead of unit dose vaccine.

c. **Additional Strategies.** The VA National Center for Health Promotion and Disease Prevention (NCP) has updated the Influenza-Pneumococcal Resource Toolkit; it is available at website http://www.vaprevention.com or http://vaww.nchpdp.med.va.gov . For additional strategies to implementing recommendations in health care settings, see "Recommendations of the Advisory Committee on Immunization Practices (ACIP)," Morbidity and Mortality Weekly Report (MMWR), May 28, 2004, pages 20-21 (http://www.cdc.gov/mmwr/pdf/rr/rr5306.pdf).

9. LIVE, ATTENUATED INFLUENZA VACCINE (LAIV)

a. The LAIV licensed for use in the United States is a live attenuated vaccine administered intranasally for the prevention of disease caused by influenza A and B viruses and is approved for use only in healthy persons ages 5 through 49 years. LAIV is administered by a small volume intranasal spray of liquid containing live, but weakened, influenza virus.

b. The following populations should not be vaccinated with LAIV:

(1) Persons ages less than 5 years old and persons ages 50 years old or older.

(2) Persons with asthma, reactive airways disease, or other chronic disorders of the pulmonary or cardiovascular systems; or

(3) Persons with other underlying medical conditions including such metabolic diseases as diabetes, renal dysfunction, and hemoglobinopathies; or

(4) Persons with known or suspected immunodeficiency diseases or who are receiving immunosuppressive therapies;

(5) Children or adolescents receiving aspirin or other salicylates (because of the association of Reye syndrome with wild-type influenza infection;

(6) Persons with a history of GBS;

(7) Pregnant women; or

(8) Persons with a history of hypersensitivity, including anaphylaxis, to any of the components of LAIV or to eggs.

c. Severely immunocompromised persons should not administer LAIV.

d. Inactivated vaccine is preferred over LAIV for vaccinating household members, health care workers, and others who have close contact with severely immunosuppressed persons during periods when such persons require care in a protected environment.

e. The many published exclusions for LAIV, including the age restrictions, chronic illness restrictions, and the risk that the vaccine virus could be shed and infect others mean that many VA patients and employees are among those who should not be vaccinated against influenza with LAIV. Use of inactivated influenza vaccine (the "flu shot") is preferred for VA employees. For these reasons, VA does not plan to use LAIV for employee vaccination.

f. Because employees may choose to be vaccinated with LAIV by their own health care provider, these employees, together with their supervisors and appropriate local VA facility experts in Occupational Health, Infection Control, or Infectious Diseases, review the employee's

working situation to assess the risk of transmitting LAIV virus to others in the workplace. If this is the case, a determination may be made to change the employee's duties temporarily or to recommend that the employee take sick or annual leave for the period of possible viral shedding (thought to be 7 days after vaccine receipt). This determination is most likely to be made for the employee who has close contact with severely immunosuppressed patients (e.g., patients with hematopoietic stem cell transplants).

g. Hospital visitors who have received LAIV should refrain from contact with severely immunosuppressed persons for 7 days after vaccination.

h. For issues pertaining to precautions to be taken post-LAIV vaccination, consult the package insert.